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HHS FOR FDA - LUMPKIN, PLAISER, FRASER

E.O. 12958: N/A

TAGS: ETRD EAGR ECON IT EUN EXPORT CONTROLS
SUBJECT: ITALY'S ONGOING CONCERNS REGARDING U.S.
BIOTERRORISM ACT

REFTEL: 03 ROME 4872

- 11. Summary. GOI officials continue to raise concerns about the U.S. Bioterrorism Act (BTA), in particular the burden it places on Italian small- and medium-size exporters, whose products make up a significant portion of Italys food exports. Officials from three ministries emphasized to Embassy officials in two meetings February 4 their close attention to the ongoing implementation of BTA. In addition, Embassys DHS/Bureau of Immigration and Customs Enforcement office has fielded numerous inquiries
- from both exporters and shipping companies regarding the potentially negative impact of BTA on their activity. The GOI has requested additional seminars on BTA by DHS/Bureau of Customs and Border Protection (DHS/BCBP) officials in Italy to follow-up the successful seminars held in Rome and Milan last October. End summary.
- 12. The Italian Agriculture Ministry called a meeting on February 4, attended by MFA and Foreign Trade officials, as well as Embassy Rome offices involved with outreach FAS and DHS/Bureau of Immigration and Customs Enforcement (DHS/BICE). MinAg officials said that the BTA has placed a heavy burden on SME exporters. Italys numerous small-and medium-size food exporters are concerned about the costs associated with contracting a U.S. agent. FAS pointed out that the U.S. Government does not collect fees associated with contracting for agents, and suggested that Italian trade organizations might work out ways to reduce such costs. The GOI also views the application of the BTAs provisions to individuals shipping items to relatives and friends in the U.S. as excessively bureaucratic.
- 13. Italian exporters have also expressed to the GOI their confusion regarding the timing of full implementation of the BTA. Embassy explained that while the prior notice provision became effective on Dec. 12, 2003, the U.S. Food and Drug Administration had agreed to phase-in full enforcement of the new rules by August 12, 2004. Notwithstanding the current leniency on enforcement, exporters should now make every effort to comply with the rules. Repeat offenders are more likely to be subject to penalties.
- 14. Officials of the MFAs Directorate General for European Integration (which handles EU affairs) noted that the BTAs provisions on records maintenance could be seen as unduly interfering in an area beyond U.S. jurisdiction, by imposing a traceability system on non-U.S. entities. FAS suggested that governments in fact ct
- may require foreign producers to comply with certain food safety standards in the production of foods to be consumed by its citizens. FAS recalled the example of the EU certified slaughter houses in the U.S., for the production of meat to be exported to member states.
- 15. After answering other routine questions raised by the GOI, FAS and DHS/BICE offered cooperation with GOI authorities on future questions or clarification. The GOI MinAg offered to put together a list of specific questions that would be forwarded to FDA through US Embassy Rome.
- 16. In a separate meeting February 4 with econoffs, Ministry of Productive Activities Foreign Trade officials Sandro Fanella and Stefano Santacroce underscored their ministrys continued close attention to BTA implementation. Supporting Italian SMEs is a prime concern of the Ministry, given these firms relatively high importance (by EU standards) to the Italian export sector. Such GOI support has been manifested for years s
- by its keen interest in expanding the protection of geographic indications, also for the benefit primarily of SME exporters.
- 17. DHS/BICE officials in Italy have registered a variety of concerns about BTA from Italian exporters. Small manufacturers have experienced difficulty because of the

language barrier (none of the instructions are available in Italian), and are often unfamiliar with the processing

of electronic paperwork on the Internet, such as obtaining prior notice confirmation numbers. We have also heard complaints about U.S. law firms offering their services as U.S. agents for exporters, often at great expense. Some exporters are wary of disclosing business confidential information to agents with whom they are

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largely unfamiliar. The Italian trade promotion agency ICE (Istituto Commercio Estero) has attempted to help Italian exporters in this regard by screening some of the companies offering their services as agents, and by making available to exporters a list of such agents.

- 18. Shipping/forwarding companies have also raised a variety of concerns with us. Some are unsure about their legal responsibility in case a shipment is rejected (especially when such rejection or delay is due to missing or incomplete information), as well as the costs to be borne for a rejection or delay. A shipping company could find itself responsible for the problems deriving from a blocked shipment even if such problems are due to another companys errors. Shippers worry they will bear the brunt of security costs imposed on them by the BTA, since security burdens are not equitably shared among the various entities in the export chain. The shipping/forwarding industry is highly competitive. With the cost of retrieving information in Europe higher than in many other parts of the world, European firms believe theyre at a competitive disadvantage versus firms in such places as Hong Kong.
- ¶9. Another major concern is the role and responsibility y of the U.S. agent. Many manufacturers complain that having a single U.S. agent could discriminate against exporters, since there are geographically distinct distribution systems in the U.S., especially between the east and west coasts. In addition, a manufacturer might not want to disclose details of its sales practices to different U.S. distributors.
- 110. Comment. Recent meetings have underscored the GOIs attention, if belatedly, to the BTA and its potential impact on Italian food exporters. Despite Embassys outreach in the last year, the GOI until recently had not substantively engaged the Embassy on its concerns regarding BTA. Italian exporters, on the other hand, have long sought information on BTA, as seen by their heavy attendance at the two BTA seminars given by DHS/BCBP last October. (Embassy would welcome additional such seminars this year if possible). Given the GOIs particular interest in protecting its small- and mediumsized agricultural exporters (as evidenced by its strong ng

stand on expanding protection of geographic indications), we expect Italy would strongly support any EU-level approaches to the U.S. on the trade implications of BTA on European exporters. End comment.

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